UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,109	03/04/2002	Rosa Maria Perez Gomariz	G80-016 CIP	5154

21706 7590 11/17/2003

NOTARO AND MICHALOS
100 DUTCH HILL ROAD
SUITE 110
ORANGEBURG, NY 10962-2100

EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,109	PEREZ GOMARIZ ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- Th MAILING DATE of this communication appears on the c ver sh et with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *2-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/4/2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/446,352* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claim 1 filed on September 12, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. For example, see the specification, page 7, third paragraph. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

3.

Drawings

4. Label "C" and "0" in Figure 7 are overlapped . Applicant is required to replace with a new Figure 7 in response to this office action.

Sequencing listing

5. The examiner notes that this instant application contains a paper copy of "Sequencing Listing" and a copy of "Sequencing Listing" in computer readable form which is good

technically and has been entered into PTO database. However, these peptide sequences in the Sequencing Listing are not found in the specification. Furthermore, the examiner notes that the specification of this instant application also contains several nucleic acid probes with more than ten nucleotides (see pages 16 and 17) and two peptide sequences ([K15, R16, L27]VIP(1-7)/GRF(8-27) and Ro 25-1553) with more than four amino acids (see page 20, first paragraph), which are not listed on the paper copy of "Sequencing Listing" and the copy of "Sequencing Listing" in computer readable form.

Appropriate correction is required.

Specification

6. The disclosure is objected to because of the following informalities: (1) applicant claims priority for parent case 09/446,352 in the first sentence of the specification. Since the case 09/446,352 now is US Patent No.6,429,188 B1, applicant is required to update the status of the case 09/446,352 in the first sentence of the specification; and (2) at page 13 of specification, there is provided description for Figure 8. Upon reviewing the figures, however, there are Figures 8A-8D. Each figure, e.g. 8A, is considered to be a separate figure and needs to be described in the specification.

Appropriate correction is required.

Claim Objections

7. Claim 1 is objected to because of the following informalities: (1) Note that "VPAC1" is an abbreviation. It can only be used after whole name of "VPAC1" appears once. It is known in

the art that the whole name of "VPAC1" is vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor 1; and (2) "VPAC1 receptor agonist" should be "a VPAC1 agonist" or "VPAC1 agonists"

Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fishbein *et al.*, (Peptides, 15, 95-100, 1994).

Fishbein *et al.*, teach a chimeric VIP-PACAP analogue but not VIP pseudopeptides function as VIP receptor antagonists. Since pseudopeptides [ψ2-3]VIP, [ψ3-4]VIP, [ψ4-5]VIP, [ψ5-6]VIP, [ψ6-7]VIP, and [ψ8-9]VIP are agonists of VIP receptor with different binding affinities (see abstract in page 95 and Table in page 98) and it is known that VPAC1 receptor are one of VIP receptors (see the specification, page 7, third paragraph), pseudopeptides [ψ2-3]VIP, [ψ3-4]VIP, [ψ4-5]VIP, [ψ5-6]VIP, [ψ6-7]VIP, and [ψ8-9]VIP taught by Fishbein *et al.*, are VPAC1 receptor agonists as recited in claim 1. Since pseudopeptides [ψ2-3]VIP, [ψ3-4]VIP, [ψ4-5]VIP, [ψ5-6]VIP, [ψ6-7]VIP, and [ψ8-9]VIP are purified by analytical reverse-phrase HPLC (see page 96, right column, first paragraph), after the purification, pseudopeptides [ψ2-

3]VIP, [ψ3-4]VIP, [ψ4-5]VIP, [ψ5-6]VIP, [ψ6-7]VIP, and [ψ8-9]VIP are in a HPLC loading buffer. According to the definition of pharmaceutically acceptable carrier in the specification (see page 14, lines 7-19), the HPLC loading buffer is considered as a pharmaceutically acceptable carrier as recited in claim 1. One or more above pseudopeptides and the HPLC loading buffer taught by Fishbein *et al.*, are components of a pharmaceutical composition as recited in claim 1. Although Fishbein *et al.*, do not show that the pharmaceutical composition comprising one or more above pseudopeptides in the HPLC loading buffer can used for the treatment and/or prevention of septic shock as recited in claim 1, the effect of the pharmaceutical composition recited in claim 1 in the treatment and/or prevention of septic shock is considered as an intended use of the pharmaceutical composition recited in claim 1. It is known that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

Therefore, Fishbein *et al.*, teach all limitations recited in claim 1.

10. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Xia *et al.*, (Peptide , 18, 1539-1549, December 1997).

Xia *et al.*, teach development of high affinity selective VIP1 receptor agonists. Since two VIP receptor agonists, [R16]chicken secretin and [K15, R16, L27]VIP(1-7)/GRF(8-27), have much stronger affinity for VIP1 receptor than VIP 2 receptor (see abstract in page 1539 and right

column in page 1544) and it is known that VIP1 receptor and VPAC 1 are identical, [R16]chicken secretin and [K15, R16, L27]VIP(1-7)/GRF(8-27) taught by Xia *et al.*, are two VPAC 1 agonists. Since [R16]chicken secretin and [K15, R16, L27]VIP(1-7)/GRF(8-27) taught by Xia *et al.*, are purified by a reverse-phrase chromatograph, after the purification (see page 1541, left column last paragraph), R16]chicken secretin and [K15, R16, L27]VIP(1-7)/GRF(8-27) are in a loading buffer from the reverse-phrase chromatograph. According to the definition of pharmaceutically acceptable carrier in the specification (see page 14, lines 7-19), the loading buffer from the reverse-phrase chromatograph is a pharmaceutically acceptable carrier as recited in claim 1. [R16]chicken secretin or/ and [K15, R16, L27]VIP(1-7)/GRF(8-27), and the loading buffer from the reverse-phrase chromatograph are components of a pharmaceutical composition as recited in claim 1. Although Xia *et al.*, do not show that the pharmaceutical composition comprising [R16]chicken secretin or [K15, R16, L27]VIP(1-7)/GRF(8-27) in the loading buffer from the reverse-phrase chromatograph can used for the treatment and/or prevention of septic shock as recited in claim 1, the effect of the pharmaceutical composition recited in claim 1 in the treatment and/or prevention of septic shock is considered as an intended use of the pharmaceutical composition recited in claim 1. It is known that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

Conclusion

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
November 14, 2003